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Proposed Maximum Residue Limit PMRL2013-81

2,4-D

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has granted full registration to new end-use products containing 2,4-D (present as the choline salt) and glyphosate (present as the dimethylamine salt) for the control of annual and perennial weeds in transgenic ENLIST corn and transgenic ENLIST soybeans. The specific uses approved in Canada are detailed on the product labels of GF-2654 TC Herbicide, GF-2726 Herbicide, GF-2654 TSOY Herbicide and GF-2726 TSOY Herbicide, *Pest Control Products Act* Registrations 30957, 30958, 30959 and 30960.

The evaluation of these 2,4-D applications indicated that the end-use products have merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for 2,4-D is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I. Existing MRLs for glyphosate are adequate to cover all uses of GF-2726 Herbicide and GF-2726 TSOY Herbicide.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for 2,4-D, are as follows.

Table 1 Proposed Maximum Residue Limits for 2,4-D

Common Name	Residue Definition	MRL (ppm)	Food Commodity
2,4-D	(2,4-dichlorophenoxy)acetic acid	3.0	Kidney of cattle, goats, horses and sheep
		0.3	Fat, meat and meat byproducts (except kidney) of cattle, goats, horses and sheep
		0.05	Fat, meat and meat byproducts of hogs and poultry
		0.03	Milk
		0.01	Eggs

ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Refer to Table 2 for a comparison, where different, of the Canadian MRLs, American tolerances and Codex MRLs[1] for 2,4-D. The proposed Canadian MRL for eggs is the same as the corresponding Codex MRL. The proposed Canadian MRLs for the fat, meat and meat byproducts (except kidney) of cattle, goats, horses and sheep are the same as the corresponding American tolerances.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Kidney of cattle, goats, horses and sheep	3.0	4.0	5 (edible offal, mammalian)
Meat of cattle, goats, horses and sheep	0.3	0.3	0.2 Meat (from mammals other than marine)
Meat byproducts (except kidney) of cattle, goats, horses and sheep	0.3	0.3	5 (edible offal, mammalian)
Fat of cattle, goats, horses and sheep	0.3	0.3	No MRL established
Meat of hogs	0.05	None	0.2 Meat (from mammals other than marine)
Meat byproducts of hogs	0.05	No tolerance established	5 (edible offal, mammalian)
Fat of hogs	0.05	No tolerance established	No MRL established
Meat of poultry	0.05	No tolerance established	0.05
Meat byproducts of poultry	0.05	No tolerance established	0.5 (edible offal of)
Fat of poultry	0.05	No tolerance established	No MRL established
Eggs	0.01	No tolerance established	0.01
Milk	0.03	0.05	0.01

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for 2,4-D up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of GF-2654 TC and GF-2726 Herbicides on AAD-1 corn (ENLIST), and GF-2654 TSOY and GF-2726 TSOY Herbicides on AAD-12 soybeans (ENLIST). 2,4-D was applied at exaggerated rates to AAD-1 corn and AAD-12 soybeans, which were harvested according to label directions. In addition, processing studies conducted at exaggerated rates in treated AAD-1 corn and treated AAD-12 soybeans were reviewed to determine the potential for concentration of residues of 2,4-D into processed commodities. Residues of 2,4-D in processed commodities not listed in Table A1 are covered under the established MRL for the raw agricultural commodity (RAC) corn and under the proposed MRL for the RAC dry soybeans.

No new residue data were submitted for glyphosate. Given that the application rates for glyphosate approved for use on ENLIST corn, ENLIST soybeans, wheat, barley, rye and summerfallow are within the registered rates for glyphosate on glyphosate tolerant corn and soybeans, and for cropland use including wheat, barley, rye and summerfallow, exposure to residues of glyphosate in treated commodities will not increase for any segment of the population, and will remain acceptable and below the level of concern.

Maximum Residue Limit(s)

Table A1 summarizes the residue data used to support the proposed uses on ENLIST corn and ENLIST soybeans. Residues of 2,4-D in/on treated ENLIST soybeans will be covered under the MRL of 0.02 ppm currently under promulgation for dry soybeans, and residues of 2,4-D in/on treated ENLIST corn commodities will be covered under the MRL of 0.05 ppm established for 2,4-D in/on field corn.

TABLE A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	2,4-D Residues (ppm)		Experimental Processing Factor
			Min	Max	
Transgenic field corn grain	Pre- and Postemergence applications/3.3-3.5	73–139	<0.01	<0.01	Could not be determined as residues of 2,4-D were <0.01 ppm in corn grain and the processed commodities of refined oil, meal, grits and flour when treated at exaggerated rates
Transgenic soybean seed	Pre- and Postemergence broad applications/3.3-3.5	51–103	<0.01	<0.01	Could not be determined as residues of 2,4-D were <0.01 ppm in soybean seed and refined oil when treated at exaggerated rates

PHI = preharvest interval; ppm = parts per million

Based on the dietary burden and residue data, MRLs of 3.0 ppm in the kidney of cattle, goats, horses and sheep; 0.3 ppm in the fat, meat and meat byproducts (except kidney) of cattle, goats, horses and sheep; 0.05 ppm in the fat, meat and meat byproducts of hogs and poultry; 0.03 ppm in milk; and 0.01 ppm in eggs are recommended.

Following the review of all available data, residues of 2,4-D in transgenic field corn grain and the associated processed commodities will be covered under the MRL of 0.05 ppm established for 2,4-D in/on field corn, and residues of 2,4-D in transgenic soybean seed and the associated processed commodity will be covered under the MRL of 0.02 ppm under promulgation for 2,4-D in dry soybeans. MRLs of 3.0 ppm in the kidney of cattle, goats, horses and sheep; 0.3 ppm in the fat, meat and meat byproducts (except kidney) of cattle, goats, horses and sheep; 0.05 ppm in the fat, meat and meat byproducts of hogs and poultry; 0.03 ppm in milk; and 0.01 ppm in eggs are recommended based on the dietary burden of livestock. Residues of 2,4-D in these crop and livestock commodities at the established and proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.